

PT. MAJA AGUNG LATEXINDO

MANUFACTURE OF LATEX GLOVES

Jln. Utama No. 98 PUJI MULYO
SUNGGAL - DELI SERDANG
SUMATERA UTARA - INDONESIA

AUG 28 2008

Telp. 62-61 - 8459160
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Page Numbers 1 of 2

"510 (K)" SUMMARY

K081488

(1) Name of applicant : SIVA PRAKASH, General Manager
Address : PT. Maja Agung Latexindo
Jl. Utama No. 08, Puji Mulio, Sunggal 20352
North Sumatera - Indonesia
Phone No. : 62-61-8459170
Fax No. : 62-61-8459180

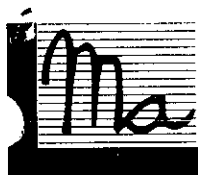
Contact person in U.S.A : Emmy Tjoeng
Phone No. : 909-591-8855
Fax No. : 909-628-6283
Email : emmyt@smcgloves.com

(2) Device details
Trade Name : Powderfree Latex Examination Gloves
Classification Name : Powderfree Latex Examination Gloves

(3) Product Code : 80 LYY

(4) Equivalent device legally marketed : Class I Examination Gloves 80 LYY
meeting ASTM D 3578-05ae2

(5) Intended use : A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.



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(6) Technological characteristic of the gloves.

a. Dimensions

| Sizes | Small | Medium | Large | X-Large | |
|------------------|-------|--------|-------|---------|----------|
| Length mm (min.) | 240 | 240 | 240 | 240 | ± 5 |
| PalmWidth mm | 80 | 95 | 105 | 110 | ± 10 |
| Thickness (min) | | | | | |
| 1. Cuff mm | 0.08 | 0.08 | 0.08 | 0.08 | |
| 2. Palm mm | 0.10 | 0.10 | 0.10 | 0.10 | |
| 3. Finger Tip mm | 0.10 | 0.10 | 0.10 | 0.10 | |

b. Physical Properties

| | Before ageing | After ageing at 70°C 168 hrs. |
|---------------------|----------------|----------------------------------|
| Tensile Strength | : 18 Mpa (min) | 14 Mpa (min) |
| Ultimate Elongation | : 650 % (min.) | 500 % (min.) |

(7) Performance data is the same as mentioned immediately above.

(8) Clinical data is not needed for gloves or for most devices cleared by the 510 (K) process.

(9) Non-clinical data

We certify that our gloves meet or exceed the ASTM D 3578-05ae2 Standard.

Meets FDA pin hole requirement.

Meets labeling claim.



AUG 28 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

PT. Maja Agung Latexindo
C/O Ms. Emmy Tjoeng
Marketing Director
Shamrock Manufacturing Company Incorporated
5445 Daniels Street
Chino, California 91710

Re: K081488
Trade/Device Name: Powder Free Latex Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: August 15, 2008
Received: August 22, 2008

Dear Ms. Tjoeng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

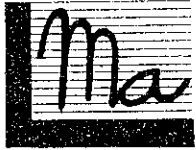
Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure



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ANNEXURE II

INDICATION FOR USE

Applicant : PT. Maja Agung Latexindo
510(k) Number (if known) : _____
Device Name : Powder Free Latex Examination Gloves
Indication for use :

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Shela *[Signature]*
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081482